In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 20-172V

LEE ANNE SENDER, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: May 21, 2024

Leah VaSahnja Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for Petitioner.

Lauren Kells, U.S. Department of Justice, Washington, DC, for Respondent.

FACT RULING ON ONSET[1]

On February 20, 2020, Lee Ann Sender filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"), alleging that she suffered a left shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine administered to her on October 4, 2017. Pet. at 1, ECF No. 1. The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

[1] Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

For the reasons discussed below, I find it more likely than not that the onset of Petitioner's shoulder pain occurred within 48 hours of vaccination.[3] However, other contested fact issues make it likely the case will require transfer out of SPU, since it has remained there without resolution for over four years, unless the parties take seriously the opportunity to settle the matter in short order.

I. Relevant Procedural History

After initiating her claim, Petitioner filed proof of vaccination, medical records, and several witness affidavits, followed by a statement of completion. ECF Nos. 6-7. In June 2020, Respondent filed a status report with his informal assessment of the claim, identifying a factual issue that may require additional development or support in the record. ECF No. 14. Specifically, Respondent noted that on February 13, 2018, Petitioner had reported that her "pain shoots down [her] arm." *Id.* at 1 (citing Ex. 3 at 103). Respondent otherwise did not identify any issues beyond what is normally addressed in SPU. *Id.* at 2. On August 24, 2020, Petitioner filed a status report confirming that "no additional factual evidence regarding her injury and its associated symptoms" exists and the "record is complete." ECF No. 18.

On May 25, 2021, Respondent filed a status report noting that he was amenable to informal resolution of the claim. ECF No. 25. But such efforts were unsuccessful. *See* ECF Nos. 26-32, 34. Accordingly, Respondent filed his Rule 4(c) Report on February 14, 2022, arguing that Petitioner had failed to show a Table injury because her medical records did not support that the onset of her pain occurred within 48 hours of vaccination. Respondent's Report at 11, ECF No. 35. Respondent also argued that Petitioner's medical records fail to demonstrate that her pain and reduced range of motion ("ROM") were limited to the shoulder in which the vaccine was administered. *Id.* Finally, Respondent asserted that Petitioner did not exhibit diminished ROM until over eleven months post vaccination. *Id.* at 12 (citing Ex. 2 at 4-8).

Petitioner subsequently filed a brief on the issues raised in Respondent's Rule 4(c) report on September 9, 2022. ECF No. 37. Approximately one month later, on October 21, 2022, Respondent filed a response to Petitioner's brief. ECF No. 38. This matter is now ripe for consideration.

[3] Although the parties submitted briefings on the issue of whether Petitioner's pain and limited range of motion were limited to the shoulder in which the subject vaccination was administered, at this time, this Ruling is limited to a finding of fact regarding onset.

II. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, 2005 WL 6117475, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Hum. Servs*., 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014). The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

III. Relevant Factual Evidence[4]

On October 4, 2017, Petitioner (then 48 years old) received a flu vaccine in her left deltoid. Ex. 1 at 2. Petitioner attests that she "immediately felt intense pain, screamed and jumped up out of [her] chair in shock." Ex. 10 ¶ 2. She states that at that time, she told the vaccine administrator and her husband "that something was really wrong." *Id.* Petitioner describes the pain as a "hot poker in [her] shoulder[.]" *Id.* Petitioner attests that she "was told it might be sore for a day, but not to worry." *Id.* She admits she "was foolishly optimistic and waited for [her] body to heal itself" but "[e]ventually," she realized she had a "serious injury requiring doctor's care." *Id.* ¶ 3.

Six weeks post-vaccination, on November 16, 2017, Petitioner had a follow-up visit with her cardiologist for pre-existing hyperlipidemia. Ex. 3 at 86-89. Petitioner made no mention of left shoulder complaints during this visit, and a physical examination of her "upper extremities" was negative for "clubbing, cyanosis, or edema." *See id.* Later that month, on November 22, 2017, Petitioner followed up with her endocrinologist for pre-existing thyroid abnormalities. *Id.* at 89. She again did not mention left shoulder complaints during this visit, and a physical examination was normal. *Id.* at 91-92.

On December 7, 2017, Petitioner presented to an internist to establish care. Ex. 3 at 93. Petitioner did not complain of left shoulder symptoms during this visit. *See id.* at 93-96. An examination revealed a left lateral "neck/shoulder with subcm [sic] lump." *Id.* at 96. The assessment included a "mass of [the] left side of [the] neck." *Id.*

Petitioner attended an endocrinology follow-up for her thyroid on February 6, 2018. Ex. 3 at 98. Similarly, Petitioner did not complain of left shoulder complaints. *Id.* at 98-102. A physical examination was normal. *Id.* at 101.

Four months and nine days post vaccination, on February 13, 2018, Petitioner presented to her primary care physician ("PCP") reporting "left arm pain s/p flu vaccine.

[4] Only those facts relevant to onset will be discussed herein, although other facts may be included as necessary.

Instant pain at time of injection [on] 10/02/17 [sic].” Ex. 3 at 103. Petitioner described the pain as “severe” with rotation and that the “[p]ain shoots down [her] arm.” *Id.* Petitioner’s musculoskeletal examination was normal, absent foot pain. *Id.* at 105. The physician noted that Petitioner “ha[d] done extensive research and found several articles detailing this injury from vaccines.” *Id.* at 106. The physician ordered an x-ray, which showed calcific tendinosis around the greater tuberosity, and Petitioner was referred to orthopedics. *See id.* at 106, 275-76.

On February 16, 2018, Petitioner had an orthopedic evaluation for “left shoulder and arm pain.” Ex. 2 at 29. During this visit, she reported “three months of left shoulder pain that started after she received a flu shot at CVS.” *Id.* Petitioner also complained that “[t]he pain radiates up and down the arm[, but s]he has no tingling or numbness in the fingers. She has no neck pain. There is no other arm pain.” *Id.* Upon examination, Petitioner exhibited tenderness over the anterolateral acromion, that increased with forward elevation and positive impingement signs, with tenderness over the rotator cuff. *Id.* at 30. The orthopedist’s impression was “left shoulder deltoid pain status post vaccination[,]” left shoulder calcific tendinitis, and “rule out left shoulder abscess.” *Id.* at 31. The orthopedist opined that Petitioner had “a calcific deposit in the rotator cuff tendon in their shoulder[, that] . . . can cause significant pressure and irritation in the rotator cuff causing a severe inflammatory reaction.” *Id.*

Petitioner underwent an MRI of her left shoulder on March 5, 2018, which confirmed the existence of a calcific deposit along the bursal surface of the supraspinatus tendon, with adjacent tendinopathy and a mild partial tear of the subscapularis tendon. Ex. 2 at 35. The MRI also showed moderate acromioclavicular joint arthropathy without significant deformity and small joint effusion with a small to moderate amount of fluid in the bursa. *Id.* at 36.

On March 8, 2018, Petitioner presented for acupuncture and trigger point injections. Ex. 3 at 107. The chief complaint was listed, in relevant part, as “neck pain[,] golf ball knot[;] left arm pain[,] gets hot to touch, possibly from vaccine from 10/4/17.” *Id.* Regarding Petitioner’s shoulder, the acupuncturist noted that the complaint “developed in October in 2017 after a flu vaccine in the left deltoid. [Petitioner d]eveloped severe sharp pain radiating to the left forearm.” *Id.* Petitioner reported a “concern[] about some post-vaccine syndrome, underlying infection, or bone chip.” *Id.* at 108. She received trigger point injections for suspected myofascial pain syndrome, calcific tendonitis of the left shoulder, chronic left shoulder pain, left forearm pain, and neck pain. *Id.* at 111.

Four days later, on March 12, 2018, Petitioner returned to her orthopedist complaining of “continue[d]” left shoulder pain “over the flu injection site” and “occasional

pain in the collar bone and the armpit." Ex. 2 at 21. A physical examination revealed tenderness over the left deltoid. *Id.* The impression was noted as "left shoulder tenderness s/p flu shot." *Id.* at 22. Petitioner was referred to physical therapy ("PT"). *Id.*

Petitioner presented for an initial PT evaluation on April 9, 2018. Ex. 2 at 42. Petitioner reported that her left deltoid pain was "residual from a flu shot in October 2017." *Id.* Petitioner also reported that her symptoms "occasionally radiate from [her] deltoid to [her] proximal forearm, down to [her] wrist." *Id.* She described the pain as constant and dull, but sharp at night or with cold weather. *Id.* The date of onset was listed as "Oct. 2017." *Id.*

During a September 11, 2018 evaluation with an orthopedic surgeon, Petitioner complained of continued left shoulder pain. Ex. 2 at 4. Petitioner stated that her pain was "dull, throbbing and sharp . . . localized in the shoulder without radiation." *Id.* The physician noted that "[t]here has been some trauma, [Petitioner] had a SIRVA vaccine into her shoulder and started having shoulder pain afterward. The vaccine was October 2017." *Id.* Upon examination, Petitioner exhibited diminished ROM in the left shoulder. *Id.* at 5. A repeat x-ray revealed no calcifications. *Id.* at 7.

On September 27, 2018, Petitioner presented for a pre-operative appointment with her PCP. Ex. 3 at 167. The physician noted that on "10/02/2018[,] [sic] [Petitioner] started w/ left shoulder pain s/p flu shot. Since then[, the pain is] constant . . . sharp, dull and [it] migrates from [the] shoulder down [her] left arm." *Id.* at 167-68.

Petitioner had a follow-up acupuncture visit on October 2, 2018, during which she reported she "was doing well until she received [a] flu vaccine on 9/27 to [right her] deltoid." Ex. 3 at 176. The acupuncturist noted that Petitioner had a history of left "shoulder/arm pain that all began after [a] flu vaccine [in] Oct. 2017 to [the left] deltoid." *Id.*

On November 1, 2018, Petitioner began post-operative PT. Ex. 4 at 19. The "date of onset/exacerbation/surgery" was listed as "10/10/18." *Id.* The chief complaint noted that Petitioner had been experiencing "pain and stiffness in [the left] shoulder since 10/10/18." *Id.* However, the visit notes also reflect that Petitioner stated her "pain started last year after getting a flu shot and it never improved with conservative management." *Id.*

Over two years and five months since her last treatment for left shoulder pain, Petitioner had a telemedicine visit with an internist on September 15, 2021. Ex. 15 at 2. Petitioner reported that she has "started with left shoulder pain" and would like to try PT.

Id. The assessment noted "left rotator cuff tear arthropathy . . . from injection[,] surgery . . . 2019[,] 6/8/2020 still pain, locking." *Id.* Petitioner was referred to PT. *Id.*

The next day (September 16, 2021), Petitioner presented for a PT evaluation, noting a "chronic history of rotator cuff injury with surgery in 2018." Ex. 16 at 1. Petitioner reported she had an "insidious exacerbation of [her] left shoulder pain 5 weeks ago." *Id.* She also reported "[m]ild radiating pain through [her] bicep." *Id.* No additional medical records have been filed.

Petitioner submitted several witness affidavits in support of her claim. Of note, Petitioner's husband, William Sender, attests that he also received a flu vaccination the same day as Petitioner and when Petitioner's was administered, "she shot out of the chair yelling how bad it hurt." Ex. 11 ¶ 1. Mr. Sender states that Petitioner "was upset and told [him] that something was wrong." *Id.* He explains, "[t]hat night, [Petitioner] took Aleve and tried ice packs and then a hot pad" to alleviate her shoulder pain. *Id.* ¶ 2. Mr. Sender attests "[t]his was the beginning of constant pain that gradually got worse for [Petitioner]." *Id.*

Additionally, three of Petitioner's friends, all of whom are nurses, submitted affidavits on Petitioner's behalf. Petitioner's friend, Patricia Monzon, attests that Petitioner "had reached out to [her] a couple of years ago on a particular day that she had obtained a flu vaccine." Ex. 13 ¶ 1. Petitioner complained to Ms. Monzon of "excruciating shoulder pain" and Ms. Monzon told her to apply ice to the area. *Id.* More so, another friend of Petitioner's, Sarah Riddle-Skelton, attests that "on the night of October 4 or during the day of October 5, 2017, [she] spoke to [Petitioner] regarding her flu vaccine that she received at CVS." Ex. 14 ¶ 1. Petitioner "was complaining [to Ms. Riddle-Skelton] of extreme pain in her shoulder where she had received the vaccine." *Id.* A third friend, Michelle Powell, attests that she had a conversation with Petitioner wherein Petitioner asked her "if it was normal to have severe pain after having a flu vaccine." Ex. 12 ¶ 1. No additional affidavit evidence has been provided.

IV. Findings of Fact regarding Onset

A petitioner alleging a SIRVA claim must show that she experienced the first symptom or onset within 48 hours of vaccination (42 C.F.R. § 100.3(a)(XIV)(B)), and that her pain began within that same 48-hour period (42 C.F.R. § 100.3(c)(10)(ii) (QAI criteria)). Respondent contends that Petitioner's medical records do not support that the onset of her pain occurred within 48 hours of vaccination. Respondent's Report at 11. Petitioner sought no treatment for more than six weeks after the subject vaccination, and she attended a total of four "intervening" medical visits before mentioning left shoulder

symptoms – at which it would have been "appropriate [] to discuss ongoing left shoulder pain." *Id.* (citing Ex. 3 at 86-102)[5]; Respondent's Response at 2-3. Respondent further highlights that when Petitioner first complained of shoulder pain linked to the subject vaccination on February 13, 2018, she admitted she had performed '"extensive research and found several articles detailing this injury from vaccines."' Respondent's Report at 11 (citing Ex. 3 at 106). More so, during Petitioner's February 16, 2018 orthopedic visit, Petitioner described her injury as '"SIRVA"' and reported pain for the last three months, or since roughly November 2017. *Id.* at 11, 11 n.4 (citing Ex. 2 at 29, 69). She thus is relying on affidavits alone to support her argument as to onset. Respondent's Response at 4-5.

Respondent has accurately observed a significant delay in treatment, but in this case it does not overcome a finding that onset likely began within the Table-defined timeframe. Although it is correct that Petitioner did not seek treatment for left shoulder symptoms for over four months post vaccination (on February 13, 2018), even *greater* delays have not undermined an otherwise-preponderantly-established showing of two-day onset. *See,* e.g., *Tenneson v. Sec'y of Health & Hum. Servs*., No. 16-1664V, 2018 WL 3083140, at *5 (Fed. Cl. Spec. Mstr. Mar. 30, 2018), *mot. for rev. denied,* 142 Fed. Cl. 329 (2019) (finding a 48-hour onset of shoulder pain despite a nearly six-month delay in seeking treatment); *Williams v. Sec'y of Health & Hum. Servs*., No. 17-830V, 2019 WL 1040410, at *9 (Fed. Cl. Spec. Mstr. Jan. 31, 2019) (noting a delay in seeking treatment for five-and-a-half months because a petitioner underestimated the severity of her shoulder injury).

Intervening care in such a gap can also be probative of onset questions – and here, the record establishes that Petitioner sought care with four treaters between the date of her vaccination and the February 13, 2018 visit. However, three of the four intervening visits were follow-up visits with specialists for pre-existing medical conditions, unrelated to Petitioner's shoulder complaints. *See* Ex. 3 at 86-89 (Petitioner's November 16, 2017 cardiology visit); Ex. 3 at 89-93 (Petitioner's November 22, 2017 endocrinology visit); Ex. 3 at 98-102 (Petitioner's February 6, 2018 endocrinology visit). Since these visits were with various specialists for chronic issues, it is not reasonable to expect a claimant to list all existing problems she may then be experiencing, even if unrelated. And while it is reasonable to assume someone suffering from persistent shoulder pain might complain of symptoms to a general internist – and Petitioner saw such a treater on December 7, 2017, (especially in light of her neck complaint) – Petitioner has offered a

[5] The "intervening visits" cited by Respondent include Petitioner's November 16, 2017 cardiology visit for hyperlipidemia, a November 22, 2017 endocrinology visit, a December 7, 2017 internal medicine visit, and a February 6, 2018 endocrinology visit. Ex. 3 at 86-102.

fair explanation, based on her assumption that she would likely recover soon from transient pain left over from the vaccination. *See* Ex. 10 ¶ 3.

Otherwise, the totality of the medical record supports the conclusion that Petitioner's shoulder pain most likely began within 48 hours of receiving her October 4, 2017 flu vaccine. Petitioner's medical records establish that she consistently and affirmatively associated her left shoulder pain to the October 2017 vaccination beginning at her first post-vaccination visit for shoulder complaints on February 13, 2018, and thereafter. *See,* e.g., Ex. 3 at 103 (a February 13, 2018 PCP visit complaining of "left arm pain s/p flu vaccine. Instant pain at time of injection [on] 10/02/17 [sic]."); Ex. 3 at 107 (a March 8, 2018 acupuncture visit note stating shoulder pain "developed in October in 2017 after a flu vaccine in the left deltoid."); Ex. 2 at 21-22 (a March 12, 2018 orthopedic visit note showing "continue[d]" left shoulder pain "over the flu injection site," with the impression listed as "left shoulder tenderness s/p flu shot."); Ex. 2 at 42 (an April 9, 2018 initial PT evaluation note reporting left shoulder pain that was "residual from a flu shot in October 2017."); Ex. 2 at 4 (a September 11, 2018 visit with an orthopedic surgeon stating "[t]here has been some trauma, [Petitioner] had a SIRVA vaccine into her shoulder and started having shoulder pain afterward. The vaccine was October 2017."); Ex. 3 at 167 (a September 27, 2018 PCP visit note reflecting on "10/02/2018[,] [sic] [Petitioner] started w/ left shoulder pain s/p flu shot."). Petitioner's medical records thus provide preponderant support for a close-in-time onset.

Only one of Petitioner's records contains a report of onset outside of the 48-hour period (Ex. 2 at 29, a February 16, 2018 appointment reporting pain for the past three months – or since November 2017). But I do not find this is enough to preponderate against a favorable onset finding. In fact, although Petitioner reported pain dating back to November 2017, Petitioner still related such pain as beginning *after* her receipt of the vaccination. Ex. 2 at 29. More so, the orthopedist's impression following that visit included "left shoulder deltoid pain status post vaccination." *Id.* at 31. This record therefore provides some support for Petitioner's claims regarding Table onset.

I also do not find that evidence Petitioner had become aware of the SIRVA injury at the time she first complained of shoulder pain suggests her onset reports are suspicious. *See* Respondent's Report at 11 (citing Ex. 3 at 106). It is just as likely that Petitioner's own "research" into the matter made her realize the nature of the pain she had been experiencing. It is otherwise speculative under the facts of this case to attempt to factor Petitioner's motives into resolution of the onset question (which, as noted above, has preponderant support – albeit barely).

Unfortunately, resolution of onset does not resolve entitlement – as there remain thorny fact issues specific to whether the core SIRVA itself can be established, and those issues may require amplification via experts. And this matter has already stayed in SPU far too long, and with the parties unable to breach their differences despite due opportunity. Accordingly, I encourage the parties to make a *final* attempt at settlement – one that contemplates the potential litigative risk of expending further costs necessary to prove elements of Petitioner's Table claim (that ultimately may not be decided in Petitioner's favor). The matter will otherwise be transferred out of SPU before the end of the summer.

Conclusion

Petitioner has established by preponderant evidence that the onset of her shoulder pain occurred within 48 hours of her October 4, 2017 flu vaccination.

Petitioner shall file a joint status report stating that she has provided Respondent with a revised settlement demand for her left-sided Table claim and the parties' efforts towards informal resolution, **by no later than Thursday, June 20, 2024.** The matter will be transferred out of SPU thereafter unless the parties can attest that settlement is likely in the near future.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master